

**BALANCED SALT- calcium chloride, magnesium chloride, potassium chloride, sodium acetate, sodium chloride, sodium citrate solution**  
**Akorn, Inc.**

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**AKORN**  
**BALANCED SALT SOLUTION**

Rx only

**DESCRIPTION**

BALANCED SALT SOLUTION is a sterile physiological solution containing calcium chloride ( $\text{CaCl}_2 \cdot 2\text{H}_2\text{O}$ ), magnesium chloride ( $\text{MgCl}_2 \cdot 6\text{H}_2\text{O}$ ), potassium chloride (KCl), sodium acetate ( $\text{C}_2\text{H}_3\text{NaO}_2 \cdot 3\text{H}_2\text{O}$ ), sodium chloride (NaCl) and sodium citrate ( $\text{C}_6\text{H}_5\text{Na}_3\text{O}_7 \cdot 2\text{H}_2\text{O}$ ). This solution is isotonic to ocular tissue and contains electrolytes required for normal cellular metabolic functions. Each 1 mL contains:

Calcium Chloride	(MW 147.02)	0.48 mg
Magnesium Chloride	(MW 203.31)	0.30 mg
Potassium Chloride	(MW 74.56)	0.75 mg
Sodium Acetate	(MW 136.08)	3.90 mg
Sodium Chloride	(MW 58.44)	6.40 mg
Sodium Citrate	(MW 294.10)	1.70 mg

Hydrochloric Acid and/or Sodium Hydroxide added to adjust pH.

Water for Injection

7.0 pH and 300 mosm/kg osmolality.

**CLINICAL PHARMACOLOGY**

Balanced Salt Solution is an isotonic solution for use in irrigating tissues of the eyes.

**INDICATIONS AND USAGE**

For use as an extraocular and intraocular irrigating solution during ocular surgical procedure involving perfusion of the eye with an expected maximum duration of less than 60 minutes.

**WARNINGS**

- NOT FOR INJECTION OR INTRAVENOUS INFUSION.
- Do not use unless product is clear, seal is intact, container is undamaged.
- Do not use if product is discolored or contains a precipitate.
- SINGLE patient use only. The contents of this bottle should not be used in more than one patient.
- This solution contains no preservative; unused contents should be discarded.

**PRECAUTIONS**

Open under aseptic conditions only.

Prior to use, check the following: tip should be firmly in place, irrigating needle should be properly seated; squeeze out several drops before inserting into anterior chamber. The needle should be removed from the anterior chamber prior to releasing pressure to prevent suction.

Studies suggest that intraocular irrigating solutions which are iso-osmotic with normal aqueous fluids should be used with caution in diabetic patients undergoing vitrectomy since intraoperative lens changes have been observed.

There have been reports of corneal clouding or edema following ocular surgery in which Balanced Salt Solution (Sterile Irrigating Solution) was used as an irrigating solution.

## **ADVERSE REACTIONS**

Irrigation or any other trauma to the corneal endothelium may result in corneal swelling or bullous keratopathy. Postoperative inflammatory reactions as well as incidents of corneal edema and corneal decompensation have been reported.

## **DOSAGE AND ADMINISTRATION**

**18 mL bottle:** The adaptor plug is designed to accept an irrigating needle. Tissues may be irrigated by attaching the needle to the bottle as explained below. External irrigation may be done without the irrigating needle.

### **Method for Using Adaptor Plug for Ophthalmic Irrigating Needle:**

1. Aseptically remove bottle from pouch by peeling backing.
2. Snap on surgeon's sterile irrigation needle. Push until firmly in place.
3. Test assembly for proper function before use.

## **HOW SUPPLIED:**

NDC 17478-920-19 18 mL bottle

**STORAGE:** Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Avoid exposure to excessive heat and do not allow to freeze.

## **AKORN**

Manufactured by: **Akorn, Inc.**

Lake Forest, IL 60045

BLA0N Rev. 10/16

Principal Display Panel Text for Container Label:

NDC 17478-920-19 Akorn Logo

BALANCED

SALT SOLUTION

Rx only

NOT FOR INJECTION

OR INTRAVENOUS USE.

18 mL Sterile Single Dose Bottle

NDC 17478-920-19 

Usual Dosage: See package insert  
for dosage information.

# BALANCED SALT SOLUTION

R<sub>x</sub> only

NOT FOR INJECTION  
OR INTRAVENOUS USE.

18 mL Sterile Single Dose Bottle

Akorn, Inc.  
Lake Forest, IL 60045

Warning: Do not use unless product is clear,  
seal is intact and container is undamaged.

Storage: Store at 20° to 25°C (68° to 77°F).  
[see USP Controlled Room Temperature].

BSAKL Rev. 05/08



(01)00317478920199

LOT

EXP.

Principal Display Panel Text for Carton Label:

NDC 17478-920-19 Akorn Logo

BALANCED SALT SOLUTION

30 Sterile Single Dose Bottles (18 mL each)

NOT FOR INJECTION OR INTRAVENOUS USE.

NDC 17478-920-19



# BALANCED SALT SOLUTION

30 Sterile Single Dose Bottles (18 mL each)

**NOT FOR INJECTION OR INTRAVENOUS USE.**

**Usual Dosage:** See package insert for dosage information.

**Storage:** Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

**Warning:** Do not use unless product is clear, seal is intact and container is undamaged.

**R<sub>x</sub> only**

**Akorn, Inc.**

Lake Forest, IL 60045

BSAKS Rev. 05/08



LOT

EXP.

## BALANCED SALT

calcium chloride, magnesium chloride, potassium chloride, sodium acetate, sodium chloride, sodium citrate solution

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:17478-920
Route of Administration	OPHTHALMIC		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Calcium Chloride</b> (UNII: M4I0D6VV5M) (calcium cation - UNII:2M83C4R6ZB)	Calcium Chloride	0.48 mg in 1 mL
<b>Magnesium Chloride</b> (UNII: 02F3473H9O) (magnesium cation - UNII:T6V3LHY838)	Magnesium Chloride	0.3 mg in 1 mL
<b>Potassium Chloride</b> (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152)	Potassium Chloride	0.75 mg in 1 mL
<b>Sodium Acetate</b> (UNII: 4550K0SC9B) (SODIUM CATION - UNII:LYR4M0NH37)	Sodium Acetate	3.90 mg in 1 mL
<b>Sodium Chloride</b> (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37)	Sodium Chloride	6.40 mg in 1 mL

Sodium Citrate (UNII: 1Q73Q2JULR) (SODIUM CATION - UNII:LYR4M0NH37)		Sodium Citrate	1.70 mg in 1 mL	
Inactive Ingredients				
Ingredient Name		Strength		
Hydrochloric Acid (UNII: QTT17582CB)				
Sodium Hydroxide (UNII: 55X04QC32I)				
Water (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17478-920-19	1 in 1 POUCH	09/27/2006	
1		18 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA		ANDA075503	09/27/2006	

**Labeler** - Akorn, Inc. (117696770)

**Registrant** - Akorn Operating Company LLC (117693100)

## Establishment

Name	Address	ID/FEI	Business Operations
Akorn, Inc.		117696832	MANUFACTURE(17478-920) , ANALYSIS(17478-920) , STERILIZE(17478-920)

## Establishment

Name	Address	ID/FEI	Business Operations
Akorn, Inc.		117696790	REPACK(17478-920) , RELABEL(17478-920) , LABEL(17478-920) , PACK(17478-920)